REMARKS

In the present Office Action, the Examiner has made final rejections of the claims under 35 U.S.C.§112, first and second paragraphs, and has withdrawn the objections to the specification and rejections under 35 U.S.C.§103(a) over Hough et al. in the previous Office Action of October 21, 2003.

The Applicant will now respond to the Examiner's rejections below:

Rejections under 35 U.S.C.§112, first paragraph

The Examiner rejected claims 62-127 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states in the rejection at page 2, lines 17-24 that the specification does not describe a process of carrying out the four stages of forming different emulsions, in combination with selecting from four different mechanisms as claimed for forming the different pore structures. Applicant respectfully traverses this rejection.

At the outset, Applicant indicates that the general invention, described in independent claims 62 and 63 define the following steps:

1) Select emulsion composition (basic composition, optionally includes water soluble polymers in aqueous phase or hydrophobic oils in oil phase (coalescence), optionally include oil phase fillers (nano-pores); and create the emulsion (vary dosing and a mixing rate, time, etc according to example A);

2) Homogenize (manipulates emulsion properties);

3) Lay up components (single phase or first, co-extrude, and optionally include fibres for micro-capillary formation); and

4) Polymerize using heat and/or pressure (optionally extracting fibers to make microcapillary formation). See Akay Declaration, paragraph 9.

These steps are described in detail in the examples. Specifically example A describes the generic process for preparing an emulsion, example A1 describes the different dosing conditions which effect production of Basic pores of differing pore sizes, example A2 discloses a modification to the emulsion used, thereby generating Coalescence pores during polymerization, using a different mechanism, with dosing time and homogenization time of 600 seconds, still following the generic method of example A. The composite of example A2 comprises both Coalescence pores and an amount of Basic pores. The description at page 11 discloses the further modification of examples A and A1 to include filler in the oil phase, whereby a composite may be obtained comprising both Nano-pores, and Basic pores. Finally in relation to Claim 62, throughout the specification different zones of pore types are described, and the description at page 18 discloses the preferred mechanism for obtaining this, by co-extrusion of different emulsions. Also in relation to Claim 63, example C discloses creating Micro-capillaries by polymerizing the various emulsions about a 3-D network of fibers.

It is important to note that the structure of the Coalescence pores are different from the Basic pores and Coalescence pores cannot be obtained through coarse emulsions – that is to say, the Coalescence pores do not simply derive from large pore emulsions but are generated from an additive (which causes coalescence) present in the emulsion during polymerization. Therefore, one cannot prepare a composite with a region of Basic pores and a region of Coalescence pores by co-extrusion of a large and fine emulsion, but rather by co-extrusion of a fine Basic emulsion and a Basic emulsion modified by inclusion of water-soluble polymers in aqueous phase or hydrophobic oils in oil phase.

As stated in the Applicant's Declaration, the technical difference between Basic and Coalescence pores, lies in the emulsion composition. By including water soluble polymers in the aqueous phase or hydrophobic oils in the oil phase of the emulsion, and

conducting Basic pore type emulsion formation and polymerizing as with the Basic pore type procedure, the added components in the emulsion coalesce the dispersed phase droplets in the emulsion during the polymerization stage, i.e. they cause the dispersed droplets to recombine, thereby creating very large droplets of non-polymerizable material about which the monomers present in the emulsion polymerize. See Akay Declaration, paragraph 10.

For completeness, a similar mechanism is used for Nano-pore formation, but in this case an oil phase filler creates minute pores within the intervening pore walls between Basic and Coalescence type pores. On subsequent extraction of this filler a minute Nano-porosity is created about the Basic and Coalescence pores and indeed about the Micro-capillaries. Applicants refer the Examiner to the description at page 10, line 26, to page 11, line 10, for a more complete description of this. See Akay Declaration, paragraph 12.

Basic pores with controlled pore size: The oil and aqueous phases should not contain any additional material, which can change the solubility of the monomer or cause emulsion breakdown. However, if small quantities of additional material used, the primary pores are still obtained. The 'smallness' of the amount is dependent on the molecular weight of the water-soluble polymer or the hydrophilicity of the oil (co-monomer) used in the oil phase. The specification examples clearly illustrate these changes. Mixing conditions are used to determine the desired pore size. The creation of primary pores with controlled size (Example A) essentially requires the evaluation of emulsion stability diagram in terms of dosing time and mixing. This was present in the thesis by (Vikki Price, now Vikki Byron, PhD Thesis, Newcastle University, 2000 (not accessible until 2005). Applicants cite a new paper based on this patent. See Akay Declaration, paragraph 15.

If coalescence or nano-pores are desired, use oil phase and/or aqueous phase additives as exemplified in the specification. Since coalescence takes place during polymerization, controlling the size of the emulsion droplets can control the degree of

coalescence. If the droplets are small, the size of the coalescence pores will be small. Therefore the size of the coalescence pores can be controlled by controlling the emulsion droplet size as described earlier. See Akay Declaration, paragraph 11.

The creation of a 3D network of continuous capillaries is achieved by using a special mold with a network of continuous fibres arranged in a desired architecture. The emulsion is then pumped into the mold and the emulsion is allowed to polymerize. The size of the pores is again dictated by the size of the emulsion droplets and the capillary pores are dictated by the fiber diameters. In order to create an emulsion with a uniform size distribution, use of the homogenization stage is desirable where the emulsion after the dosing period is mixed further prior to polymerization. See Akay Declaration, paragraph 13. It is believed that adequate support for the written description of claims 62-127 has been provided either by indicating where in the specification the examples support the claimed invention or further by statements of the inventor in the accompanying declaration under 37 C.F.R. §1.132, and as such, Applicant respectfully requests this rejection be withdrawn.

The Examiner also rejected claims 62-127 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the claims contain subject matter, which was not described in the specification in such a way as to enable one of skill in the art to which it pertains to make or use the invention. Specifically the Examiner has made the following points:

1) The specification fails to disclose a four-stage process as claimed of forming different emulsions, homogenizing, co-extruding and polymerizing to form a plurality of zones using four different mechanisms for forming pore structure;
2) The specification does not describe using conditions as now required by the dependent claims when carrying out the process now required by claim 62;
3) Working examples have not been provided as required by claim 62 and for modifying this process as required by the dependent claims;

4) Specific details have not been provided of how different emulsions are formed in the same process and then co-extruded; and

5) It is uncertain as to apparatus that is used to form the different emulsions and for co-extrusion of the emulsion. See Akay Declaration, paragraph 9.

Applicant respectfully traverses these rejections. Applicant points to the specification and the Declaration by Dr. Akay in response to these rejections.

Specifically, most of points 1-5 are already addressed by Applicant in response to the previous rejection. Applicant also states that working examples (as stated at page 3, line 21 of the Office Action) are not a requirement for patentability. However, Applicant believes that sufficient examples of the process are disclosed in the specification as discussed above. For example, example A refers to the generic emulsion preparation, example A1 to manipulating the emulsion of example A to create Basic pores, example A2 relates to manipulating the emulsion of example A and A1 to create Coalescence pores, example A3 to A6 relate to modifying the polymer properties without effecting pore type, example B7 to B9 relate to growing cells into the basic pore type polymers and example C relates to creating Micro-capillaries. Furthermore, example B7 is conducted on "polyhipe without and with HA" in order to demonstrate the importance of HA coating. Example B8 is conducted on "styrene/2-ethylhexyl acrylate polyhipe containing hydroxy apatite" in order to show the importance of pore size in the growth of cells within pores. This example is vital since it provides justification for controlling the pore size. Example B9 is conducted on a "styrene/2-ethylhexyl acrylate polyhipe polymer" which is 12% sulphonated. Accordingly example B7 and B8 are produced using the polyhipe of example A3, the polymer for example B9 comprises that of example A3, modified by 12% sulphonation. All cell growth experiments are conducted on Basic pore type polymer scaffolds.

With regard to point 4 above, each process leading to different pore types derived from a common generic process (example A), which is Basic type pore emulsion formation. A single Basic pore type emulsion (example A1) may be prepared, and water

soluble polymers or hydrophilic oils added to the aqueous or oil phase as a first coalescence modification, and/or an oil phase filler may be added, thereby generating an emulsion which can generate Basic, Coalescence and Nano-pores. The Basic pores are created in the first emulsion formation stage, Coalescence pores are created during the subsequent polymerization and Nano-pores are created in a subsequent solvent extraction stage of the polymer after polymerization. In the process of Claim 62, different emulsions can be created having any or all of the compositions which create Basic, Coalescence and Nano-pores after polymerization, in same or different pore sizes, which may then be co-extruded after emulsion formation and prior to polymerization and solvent extraction.

Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 62-104 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner states that claim 62 and 63 are confusing and unclear. The Examiner states that it is unclear whether the emulsions described are formed simultaneously or not. The Examiner also states that the dependent claims are confusing and unclear as to how they modify the process of claim 62. Applicants traverse this rejection.

The Applicant has described in detail how the process of claim 62 and 63 functions in the examples and in Applicant's response to the above rejections. Applicant responds that the emulsions are made at the different stages according to the specification and are clearly set out by the Applicant in the schematic diagram set forth in Applicant's Declaration.

The Examiner stated that the process of claim 63 appeared to be different that claim 62. In the process of Claim 63, a single emulsion may be formed providing any or all of Basic, Coalescence and Nano-pores in desired pore size which is then cast into a mould containing a 3-D network of continuous fibers, thereafter polymerizing and

extracting the fibers to create Micro-capillaries in a single or multi-pore system. In this process two or more emulsions may be co-extruded into a mould containing a network of fibers, thereby creating a scaffold having zones of different pore types with penetrating Micro-capillaries. This is described in Claims 62 and 63 by the wording "in a first stage", "in a second stage", "in a third stage", and "in a fourth stage". Support is found for example at the description page 26 lines 19 to 21 "the method employs one or more stages as hereinbefore defined for creating type one to four pores". Also throughout, for example at page 4 lines 25 to 27 and in particular at page 7 lines 17 to 27 reference to distinct or interpenetrating zones or regions are intended to describe zones or regions which are characterized by different pore types or sizes.

Additionally, in Claim 63, a 3-D network of fibers is arranged in a mold and an emulsion is filled into the mold or in the case of multiple emulsions is co-extruded into the mould prior to polymerization. Accordingly the stages of emulsion formation and mold preparation may be conducted simultaneously, or more likely the mold preparation would be conducted first allowing the emulsion to be used immediately after preparation. In the case of Claim 62, which does not mention a 3-D network of fibbers, the multiple emulsions would be co-extruded onto a surface or into a mold without fibers being present, although the method of Claim 62 may be operated together with a network of fibers, as defined in Claim 66. See Akay Declaration, paragraph 13.

In response to the Examiner's rejection of claim 66 as (apparently) having the co-extruding element redundant from claim 62, Applicant points out that claim 66 depends from claim 63 which does not have the co-extrusion element present.

Applicant wishes to explain that the terms "Basic", "Coalescence", are capitalized to distinguish them in the context of Basic and Coalescence pores used in the specification as a type of pore, instead of their ordinary English usage. The scope and meaning of Basic pore and Coalescence pore are described in the specification and in response to the rejections above. To reiterate, the difference between Basic and Coalescence pores lies in the emulsion composition. If you take the Basic pore emulsion

formation and polymerization process, and add water-soluble polymers in the aqueous phase or hydrophobic oils in the oil phase of the emulsion, the added components in the Basic pore emulsion coalesce the dispersed phase droplets in the emulsion during the polymerization stage, i.e. they cause the dispersed droplets to recombine, thereby creating very large droplets of non-polymerizable material about which the monomers present in the emulsion polymerize, thus creating Coalescence pores.

The Examiner rejected claims 70, 73, 87, 99, 105, 106, 113 and 126 as having confusing terms such as "i.e." "directional", etc. Applicant has amended said claims and where necessary added new claims when amending claims having multiple dependencies. Claim 70 was rewritten and split into two claims with the lower temperature range written as new claim 135.

Applicant believes that all rejections have been properly overcome and the claims as amended are in condition for allowance.

If there are any questions, the Examiner is invited to call the attorney at 202-638-6666. Entry of the amendment and reconsideration is respectfully requested.

Respectfully submitted,

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